IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

LARRY W. FAIRCLOTH,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants.

Civil Action No. 2:16-5267

MEMORANDUM IN SUPPORT OF
DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

This is a case brought by the wrong party at the wrong time. Plaintiff Larry Faircloth is a consumer of electronic cigarettes and a member of the West Virginia Legislature. He challenges a U.S. Food and Drug Administration regulation—known as the "deeming rule"—that subjects e-cigarettes to regulation under the Tobacco Control Act. But that rule imposes requirements on e-cigarette manufacturers, not on consumers like Plaintiff—much less on the state of West Virginia.

Plaintiff thus complains only about hypothetical downstream effects of the deeming rule, such as reduced product availability, higher prices, and, ultimately, increased health care costs. But those sorts of indirect economic effects, even if they came to pass, would be insufficient to give Plaintiff the personal stake necessary to have standing to challenge the rule's regulation of e-cigarette manufacturers. Moreover, any such effects would be traceable not to the rule itself, but to the independent actions of third parties, such as the marketing decisions of the regulated manufacturers. And even the first step in Plaintiff's speculative chain of possibilities would not take place before August 2018, when the provision he primarily challenges will first be enforced against manufacturers.

Plaintiff's claims virtually duplicate those being litigated elsewhere by e-cigarette manufacturers who are actually regulated by the deeming rule. But the rule does not regulate Plaintiff, and he is not the appropriate party to challenge it. He lacks standing, his claims are unripe, and this case should be dismissed for lack of jurisdiction.

BACKGROUND

A. Statutory Background

The Tobacco Control Act is a comprehensive scheme for the regulation of tobacco products. Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified at 21 U.S.C. § 301 *et seq.*). Congress crafted the Act based on evidence gathered over decades by all three branches of government regarding the health risks of tobacco products and the tobacco industry's marketing practices. For example, as the Supreme Court has recognized, "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000). "Each year, 440,000 people die of diseases caused by smoking or other forms of tobacco use—that is about 20 percent of all deaths in our nation." Statement of Vice Admiral Richard H. Carmona, U.S. Surgeon General, *reprinted at* 155 Cong. Rec. S6000 (June 3, 2009). And the magnitude of this public health harm is inextricably linked to nicotine—a "powerful pharmacologic agent" with addictive properties "similar to . . . heroin and cocaine." Report of the U.S. Surgeon General (1988) at 14, *available at* https://profiles.nlm.nih.gov/ps/access/NNBBZD.pdf; *see also* 75 Fed. Reg. 69,524, 69,528 (Nov. 12, 2010). But while the tobacco industry was well aware of these risks, for decades it misled the public about the health effects and addictiveness of its products. *See, e.g., United States v. Philip Morris USA, Inc.*, 566 F.3d 1095, 1107 (D.C. Cir. 2009) ("manufacturers were aware . . . that smoking causes disease, including lung cancer," but "publicly denied and distorted the truth about the addictive nature of their products").

The Tobacco Control Act addresses the manufacture and marketing of tobacco products in three principal ways. First, Congress designed measures to ensure that manufacturers provide accurate information about the ingredients of tobacco products and their health risks. For

example, manufacturers of products subject to the Act must disclose to the FDA the identity and quantity of all ingredients—including nicotine and any other additives—in each product. 21 U.S.C. § 387d(a)(1)–(2). The labels that manufacturers place on their products must accurately describe their contents. *Id*. § 387c. Cigarettes and smokeless tobacco must bear a warning label—such as "WARNING: Smokeless tobacco is addictive," 15 U.S.C. § 4402(a)(1)—and other tobacco products may be required to bear similar warnings, 21 U.S.C. § 387f(d)(1)–(2). And to ensure that products marketed as presenting reduced health risks actually do so, Congress required premarket FDA review of tobacco products purportedly posing "modified risks," such as a lower risk of disease, or reduced exposure to a harmful substance. *Id*. § 387k.

Second, Congress took steps to control the contents and quality of tobacco products. Manufacturers must register with the FDA, *id*. § 387e(b), file a list of tobacco products they make, *id*. § 387e(i), and adhere to manufacturing practices the FDA may prescribe, *id*. § 387f(e). Given the appeal of flavored products to children, Congress banned the use of all characterizing flavors (except tobacco and menthol) in cigarettes, including "strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, [and] coffee." *Id*. § 387g(a)(1)(A). For all tobacco products, Congress authorized the FDA to adopt standards regulating the level of any ingredient, including nicotine. *Id*. § 387g(a)(3). And to avoid allowing potentially harmful tobacco products to saturate the market before regulators can catch up, as happened with cigarettes, Congress provided for premarket FDA review of new tobacco products, defined to include those entering the U.S. market after February 15, 2007. *Id*. § 387j.

Third, Congress directed the FDA to reissue, with certain changes, provisions of a 1996 rule that restricted several marketing practices used by manufacturers to recruit children and adolescents. 21 U.S.C. § 387a–1(a) (directing reissuance of portions of 21 C.F.R. part 897, now

codified at 21 C.F.R. part 1140). Among other things, for cigarettes and smokeless tobacco, that rule bans the sponsorship of concerts and athletic events in the name of a tobacco brand, and bars the distribution of merchandise bearing a tobacco brand name or logo. 21 C.F.R. § 1140.34(a), (c). And for all tobacco products subject to the Act, the rule restricts the distribution of free samples. Pub. L. No. 111-31, § 102(a)(2)(G); 21 C.F.R. § 1140.16(d).

Together, these provisions effectuate several of the Act's principal goals: to "require tobacco product manufacturers to disclose" information about "the health and dependency effects or safety of tobacco products"; to permit the FDA to "regulate the levels of tar, nicotine, and other harmful components" of tobacco products; and to ensure "effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products." Pub. L. No. 111-31, § 3(4)–(6).

B. Regulatory Background

Congress made the Tobacco Control Act applicable to four categories of tobacco products—"all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco"—as well as "to any other tobacco products that the Secretary by regulation *deems* to be subject to this chapter." 21 U.S.C. § 387a(b) (emphasis added); *cf. Webster v. Doe*, 486 U.S. 592, 600 (1988) (use of the word "deem" indicates that statute's implementation is "committed to agency discretion"). The Act "broadly defines tobacco products as extending to '*any* product made *or derived from* tobacco,'" *Sottera, Inc. v. FDA*, 627 F.3d 891, 897 (D.C. Cir. 2010) (quoting 21 U.S.C. § 321(rr)(1)), "including any component, part, or accessory," 21 U.S.C. § 321(rr)(1).

In 2010, the D.C. Circuit held that e-cigarettes meet this definition, and are therefore regulable under the Tobacco Control Act. *Sottera*, 627 F.3d at 899. E-cigarettes, sometimes known as "vaping devices," Compl. ¶ 2, are "battery-powered products that allow users to inhale

nicotine vapor," *Sottera*, 627 F.3d at 893. They generally consist of three basic parts: a cartridge of liquid typically containing nicotine extracted from tobacco ("e-liquid"), an atomizer with a heating element, and a battery and other electronics. *Id*.[1] When a user sucks on the device, the atomizer vaporizes the e-liquid, which is inhaled as an aerosol. *Id*. As the D.C. Circuit concluded, "the FDA has authority under the Tobacco [Control] Act to regulate electronic cigarettes, enabling it to mitigate or perhaps extinguish any harm to public health." *Sottera*, 627 F.3d at 899.

In the deeming rule, the FDA exercised that authority, deeming e-cigarettes—along with cigars, pipe tobacco, and other tobacco products—subject to the Tobacco Control Act. 81 Fed. Reg. 28,974 (May 10, 2016).[2] As the agency explained, e-cigarette use is spiking dramatically: they are now used by more than 13 percent of high school students, eclipsing conventional cigarettes as the most popular tobacco product among youth. *Id*. at 28,984. At the same time, e-cigarettes present significant health risks—chief among them, addiction to nicotine, which impairs brain development in youth, causes pre-term delivery and stillbirth, and can be fatal at high doses. *Id*. at 29,032–33, 29,036. Some of the 640 to 800 e-cigarette devices on the

[1] Plaintiff's blanket assertion that "E-liquids contain nicotine derived from nontobacco sources," Compl. ¶ 3, is the sort of "conclusory . . . allegation[]" that is "disentitle[d] . . . to the presumption of truth" on a motion to dismiss. *Ashcroft v. Iqbal*, 556 U.S. 662, 681 (2009). In fact, the nicotine in e-liquids is typically extracted from tobacco. *See, e.g.*, *Sottera*, 627 F.3d at 899 (the "liquid nicotine in each e-cigarette is derived from natural tobacco plants").

[2] Specifically, the FDA "deem[ed] all products meeting the statutory definition of 'tobacco product,' except accessories of the newly deemed tobacco products, to be subject to FDA's tobacco product authorities" under the Act. 81 Fed. Reg. at 28,976. The deeming rule interprets the statutory terms "component or part"—which Congress left undefined—to mean "any software or assembly of materials intended or reasonably expected: (1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics; or (2) To be used with or for the human consumption of a tobacco product," but to "exclude[] anything that is an accessory of a tobacco product." *Id*. at 29,102 (to be codified at 21 C.F.R. § 1100.3).

market—which are mostly made in China—deliver other toxic and carcinogenic chemicals, like formaldehyde and nickel, at levels higher than conventional cigarettes. *Id*. at 29,030–31. Others have exploded in users' faces, causing burns and lost teeth. *See id.* at 29,035. And while the ingredients of the staggering 4,000 to 8,000 e-liquids on the market are largely unknown, many contain diacetyl, acetyl propionyl, or various aldehydes—toxic chemicals that are especially common in candy-flavored varieties that appeal to youth. *Id*. at 29,029–31.

In view of these risks, the FDA concluded that deeming these essentially unregulated products subject the Tobacco Control Act would help mitigate any harm to public health. *Id*. at 28,984; *see Sottera*, 627 F.3d at 899. In effect, this subjects manufacturers of e-cigarettes to the same comprehensive statutory scheme that applies to manufacturers of other tobacco products, including cigarettes and smokeless tobacco. Although certain provisions of the Tobacco Control Act or the deeming rule also apply to importers, distributors, or retailers, *see, e.g.*, 21 U.S.C. §§ 387d(a), 387a–1(a)(2)(G); 81 Fed. Reg. at 29,103 (to be codified at 21 C.F.R. § 1140.10), none regulate consumers.

C. This Action

Plaintiff's complaint raises five claims. Counts I–III allege violations of the Administrative Procedure Act, 5 U.S.C. § 501 *et seq.* In Count I, Plaintiff asserts that the FDA lacks the statutory authority to deem e-cigarettes subject to the Tobacco Control Act. Compl. ¶¶ 36–38. In Count II, he argues that deeming e-cigarettes subject to the Tobacco Control Act was arbitrary and capricious because the statutory premarket review process will be "expensive and time consuming" for manufacturers, *id*. ¶ 39, and will affect manufacturers' ability "to introduce new vaping devices and e-liquids," *id*. ¶ 45; *see id*. ¶¶ 35–46. In Count III, Plaintiff claims that the FDA's cost-benefit analysis failed to recognize that "the Deeming Rule imposes

severe regulatory burdens on manufacturers" that "outweigh the benefits generated." *Id.* ¶ 51; *see id.* ¶¶ 47–52. In Count IV, he argues that two provisions—one prohibiting manufacturers from selling "modified risk" products without premarket authorization, and another forbidding manufacturers from distributing free samples—infringe an asserted First Amendment right to communicate with consumers. *Id.* ¶¶ 53–56. And in Count V, he hypothesizes that the deeming rule will prompt more West Virginians to smoke conventional cigarettes, causing state Medicaid expenditures to rise—a "compelled expenditure of . . . funds" that allegedly "deprives the State of its sovereignty" in violation of the Tenth Amendment. *Id.* ¶ 59; *see id.* ¶¶ 57–60.

Each of these claims, with the exception of the Tenth Amendment claim, is currently being litigated in a separate action brought by e-cigarette and e-liquid manufacturers and their trade associations in the U.S. District Court for the District of Columbia. *See Nicopure Labs Inc. v. FDA*, No. 16-878 (D.D.C.), *consolidated with Right to Be Smoke-Free Coalition v. FDA*, No. 16-1210 (D.D.C.). In that case—where the government has *not* challenged the manufacturers' standing, with one narrow exception[3]—summary judgment briefing is complete, oral argument has been held, and the parties are awaiting a decision.

LEGAL STANDARDS

A motion to dismiss under Rule 12(b)(1) challenges the Court's subject matter jurisdiction. In reviewing a facial challenge to subject matter jurisdiction, the Court accepts the well-pleaded allegations of the complaint as true, and determines whether those allegations are sufficient to establish jurisdiction. *Adams v. Bain*, 697 F.2d 1213, 1219 (4th Cir. 1982). However, in assessing its jurisdiction, the Court may consider extra-pleading facts, and if

[3] In *Nicopure*, the government did argue that the manufacturers lacked standing with respect to a subset of products—certain nicotine-free e-liquids—that they had not shown to be subject to the deeming rule in the first place.

necessary may resolve disputed jurisdictional facts, without converting the motion to one for summary judgment. *Id.* It is Plaintiff's burden to establish that jurisdiction exists. *Id.*

ARGUMENT

In this case, Plaintiff was not the object of any government regulation. Rather, the deeming rule operates on e-cigarette manufacturers—not on consumers, much less on the state of West Virginia. The hypothetical downstream effects of which he complains—such as reduced product availability, higher prices, and, ultimately, increased health care costs—are not only speculative but indirect, and are traceable not to the deeming rule but to the independent actions of third parties, such as the marketing decisions of the regulated manufacturers. Thus, Plaintiff fails to establish any cognizable injury, let alone one caused by the deeming rule. He therefore lacks standing—or, alternatively, his claims are unripe—and this case should be dismissed for lack of jurisdiction.

I. PLAINTIFF LACKS STANDING TO CHALLENGE THE DEEMING RULE, WHICH REGULATES E-CIGARETTE MANUFACTURERS—NOT CONSUMERS

The standing doctrine—an indispensable part of Article III's case or controversy requirement—ensures that a plaintiff has a "sufficient personal stake" in a dispute to render judicial resolution appropriate. *Friends of the Earth, Inc. v. Gaston Copper Recycling Corp.*, 204 F.3d 149, 153 (4th Cir. 2000). Because the deeming rule regulates e-cigarette manufacturers, not consumers, Plaintiff lacks such a personal stake here.

To establish Article III standing, Plaintiff must demonstrate the familiar elements of: (1) an injury in fact; (2) causation; and (3) redressability. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992). Plaintiff bears the burden "clearly to allege facts demonstrating" each of these three elements. *Warth v. Seldin*, 422 U.S. 490, 518 (1975). The necessary facts "must affirmatively appear in the record" and "cannot be inferred argumentatively from averments in

the pleadings." *FW/PBS Inc. v. Dallas*, 493 U.S. 215, 231 (1990). A complaint that is nothing "more than labels and conclusions . . . will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *see also Papasan v. Allain*, 478 U.S. 265, 286 (1986) (courts "are not bound to accept as true a legal conclusion couched as a factual allegation").

Here, Plaintiff fails to identify any cognizable injury, much less one caused by the deeming rule. The downstream economic effects about which he complains are not only speculative but indirect. Regardless, if they ever came to pass, they would be traceable not to the deeming rule, but to the independent actions of third parties, such as the marketing decisions of the regulated manufacturers.

A. Plaintiff's Alleged Injuries Are Indirect and Speculative

To establish an injury in fact, a plaintiff must identify a "distinct and palpable" harm that both (1) "affects [him] in a personal and individual way" and (2) is "actual or imminent, not conjectural or hypothetical." *Lujan*, 504 U.S. at 560 & n.1 (citations and quotation marks omitted). Here, Plaintiff meets neither of these requirements.

To begin, Plaintiff does not claim that the deeming rule burdens him directly. Rather, he alleges that (1) the rule imposes various costs on e-cigarette manufacturers, who are the parties that must comply with the "premarket approval, reporting, recordkeeping, inspection, labeling, manufacturing, testing, and other requirements imposed by the Act." Compl. ¶ 26. He then supposes that manufacturers will respond to these burdens by (2) reducing product diversity and (3) raising prices, *id.* ¶¶ 27–28, which he claims will (4) prompt him to "likely return to the unhealthy habit" of being a "2 pack per day smoker," *id.* ¶¶ 28–29, ultimately (5) increasing his "healthcare costs by an estimated $766,500" over the next "30 years," *id.* ¶ 30.

There is reason to doubt many of the links in this speculative chain of inferences. First, because Plaintiff alleges that he already uses e-cigarettes, he must *already own* the e-cigarette devices that he prefers to use, many of which are reusable and refillable. *See* Compl. ¶ 6 (Plaintiff uses "open-system vaping devices, closed system vaping devices, and e-liquids"); *id.* ¶ 4 ("open systems . . . can be refilled" and "[c]losed system products are available" with "replacement cartridges"). Second, Plaintiff does not identify the particular e-cigarettes or e-liquids that he uses, let alone demonstrate that the manufacturers of those products intend to leave the market. The FDA expects at least 266 e-cigarettes and 900 e-liquids to remain on the market after the first round of premarket review is complete, so there is no reason to believe that Plaintiff's preferred products—or close substitutes—will be unavailable;[4] indeed, Plaintiff's allegation that he uses both open and closed systems suggests that he is not wedded to any particular product. *See* Compl. ¶ 6. Third, there is no factual basis for Plaintiff's prediction that an increase in e-cigarette prices would prompt users to switch to conventional cigarettes. Plaintiff does not attempt to estimate the magnitude of any supposed price increase, nor does he allege that it will actually make e-cigarettes more expensive than his prior "2 pack per day" habit. Compl. ¶ 30. Regardless, as the FDA noted, the "elasticity of combusted cigarette consumption with respect to the price of electronic cigarettes is quite low, 0.007," which "indicates little or no response of current cigarette smoking to changes in the price of electronic cigarettes." RIA 19. Fourth, while Plaintiff suggests that this lengthy causal chain will someday lead to increased health care costs, he does not allege that he is uninsured, so he fails to show that any such costs would ultimately be borne by him, if they were ever incurred at all.

[4] *See* FDA, Final Regulatory Impact Analysis ("RIA"), at 79–80, 103 (May 2016), *available at* http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/ucm500249.htm.

This lengthy chain of inferences reveals at best a "conjectural or hypothetical" harm—not the sort of "actual or imminent" injury necessary to confer standing. *Lujan*, 504 U.S. at 560. Indeed, "[t]o allow [such] a long, intermediated chain of effects to establish standing is to abolish the standing requirement as a practical matter." *Ass'n of Am. Physicians & Surgeons, Inc. v. Koskinen*, 768 F.3d 640, 642 (7th Cir. 2014); *see also Florida Audubon Soc. v. Bentsen*, 94 F.3d 658, 670 (D.C. Cir. 1996) ("Such a protracted chain of causation fails both because of the uncertainty of several individual links and because of the number of speculative links that must hold for the chain to connect the challenged acts to the asserted particularized injury.").

Even if Plaintiff's alleged harm were more certain, it would be insufficiently direct, as such downstream economic effects are not enough to establish a cognizable injury. The Fourth Circuit's decision in *Lane v. Holder*, 703 F.3d 668 (4th Cir. 2012), is instructive. There, the plaintiffs challenged a federal statute and regulation that require interstate firearm sales to take place through licensed intermediaries (called federal firearm licensees, or FFLs). *Id*. at 670. Under that scheme, while a retailer in state A could sell a gun to a buyer in state B, the retailer would have to deliver the gun to an FFL in state B, who could then deliver it to the buyer. *Id*. at 670, 672. The plaintiffs argued that this scheme infringed their Second Amendment right to buy firearms because the FFL in state B charged them a fee. *Id*. at 671. While the Fourth Circuit recognized that the plaintiffs were "burdened by additional costs," it held that those costs were insufficiently direct to establish standing. *Id*. at 673. As it explained, consumers merely "paying the end-line cost of an economic regulation" are not injured unless they are either (1) "directly regulated by the law being challenged" or (2) "prevented outright from obtaining" the regulated product. *Id*. at 672–73. Because the firearm provisions directly regulated retailers and FFLs, not consumers, and the plaintiffs could still obtain guns, they lacked standing. *Id*. at 673.

So too here. Even accepting Plaintiff's speculative theory, he is neither "directly regulated" by the deeming rule nor "prevented outright" from obtaining e-cigarettes. *See id*. at 672–73. At most, he alleges that he would bear some of the "end-line cost" of regulations that operate on manufacturers—an indirect effect that is insufficient to confer standing. *See id.* at 672.

B. Plaintiff's Alleged Injuries Are Not Traceable to the Deeming Rule

Even if Plaintiff could demonstrate a cognizable injury in fact, he would lack standing for another, independent reason: lack of causation. To show causation, a plaintiff must establish that his injury is "fairly . . . trace[able] to the challenged action of the defendant, and not . . . the result [of] the independent action of some third party," *Lujan*, 504 U.S. at 560—a hurdle that is "substantially more difficult" to overcome where the "plaintiff is not the direct subject of government action, but rather the asserted injury arises from the government's allegedly unlawful regulation . . . of someone else," *Lane*, 703 F.3d at 673 (citation and quotation marks omitted). Here, any alleged harm is traceable not to the deeming rule, but instead to the independent actions of e-cigarette manufacturers—or to Plaintiff's own plans to resume smoking despite its health risks and financial costs.

The Fourth Circuit's decision in *Lane* again points the way. There, the court found that, even if the plaintiffs had been injured, "the costs [they] complain of are not traceable to the laws they challenge, but to the FFLs that charge transfer fees." *Lane*, 703 F.3d at 674. Because "[n]othing in the challenged . . . regulations directs FFLs to impose such charges," the FFLs' independent decision to do so "breaks the causal chain." *Id*. This case is no different. While some e-cigarette manufacturers could choose to raise prices in an attempt to pass along compliance costs, certainly nothing in the deeming rule *directs* them to do so. Absent that

crucial link, Plaintiff is "unable to demonstrate traceability." *Id.*; *see also Common Cause v. Dep't of Energy*, 702 F.2d 245, 251 (D.C. Cir. 1983) ("where injury is alleged to occur within a market context, the concepts of causation and redressability become particularly nebulous and subject to contradictory, and frequently unprovable, analyses").

In any event, even if the Court were to assume *arguendo* that the deeming rule would increase e-cigarette prices, Plaintiff's causal chain would still fail at the last link. The crux of his argument is not that e-cigarettes will cost him more, but that higher prices will cause him to abandon e-cigarettes and resume smoking, potentially leading to increased health care expenses over some "30 years." Compl. ¶ 30. But a plaintiff cannot obtain standing by alleging "only an injury at some indefinite future time," particularly where "the acts necessary to make the injury happen are at least partly within the plaintiff's own control." *Lujan*, 504 U.S. at 564 n.2. Plaintiff is well aware that smoking is "dangerous" and can result in "increase[d] . . . health care costs," which is presumably why he "quit using . . . cigarettes." Compl. ¶¶ 29–30. And there are several proven smoking cessation aids on the market, such as nicotine-replacement gum, patches, and lozenges.[5] If Plaintiff nevertheless resumes smoking, despite its grave health risks, then the financial consequences cannot be traced to the deeming rule. *See, e.g.*, *Johnson v. U.S. Office of Pers. Mgmt.*, 783 F.3d 655, 667–68 (7th Cir. 2015) (plaintiffs "cannot allege an injury from one of [multiple] options where they can choose another which causes them no injury"); *cf. Clapper v. Amnesty Int'l USA*, 133 S. Ct. 1138, 1151 (2013) (plaintiffs "cannot manufacture standing merely by inflicting harm on themselves"); *Nat'l Family Planning & Reprod. Health Ass'n v. Gonzales*, 468 F.3d 826, 831 (D.C. Cir. 2006) ("self-inflicted harm . . . does not amount to an

[5] *See* FDA, Smoking Cessation Products, *at* http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm198176.htm#replacement.

'injury' cognizable under Article III" and "would not be fairly traceable to the defendant's challenged conduct").

C. Plaintiff's Status as a Taxpayer or State Legislator Gives Him No Greater Standing

Plaintiff's status as a taxpayer or state legislator gives him no greater standing to challenge the deeming rule. Plaintiff hypothesizes that the rule will not only affect his *own* health care costs, but will also prompt *other* West Virginians to smoke, causing state Medicaid expenditures to rise—a "compelled expenditure of . . . funds," Compl. ¶ 57, that will allegedly "drive[] up state tax costs," *id*. ¶ 32, and "deprive the State of its sovereignty," *id*. ¶ 57. But even assuming that an individual, rather than a state, could bring such a "commandeering" claim under the Tenth Amendment, Plaintiff must nevertheless satisfy the usual "Article III requirements, as well as prudential rules, applicable to all litigants and claims," including a personalized injury. *Bond v. United States*, 564 U.S. 211, 225 (2011). "Individuals have 'no standing to complain simply that their Government is violating the law.'" *Id*. (citation omitted).

Here, Plaintiff lacks standing to complain about the deeming rule's supposed effect on state coffers for the same reasons he lacks standing to challenge the deeming rule generally: he fails to establish any cognizable injury traceable to the rule. *See supra* Parts I.A–B. Indeed, if anything, his commandeering theory is even more tenuous, for it adds yet another link to an already brittle causal chain—namely, that allegedly higher prices will not only drive e-cigarette users back to smoking, but that these smokers will incur greater health care costs, requiring the state of West Virginia to increase its Medicaid spending and raise taxes. *See* Compl. ¶ 33. As noted above, there is no factual basis for these dire predictions, as the elasticity of demand for smoking with respect to e-cigarette prices is nearly zero. *See supra* at 10. Nor is there any reason to conclude that such consequences are "imminent"—that is, "certainly impending."

DaimlerChrysler Corp. v. Cuno, 547 U.S. 332, 345 (2006). And because the FDA does not intend to enforce the Act's premarket review requirement—which Plaintiff blames for most of the deeming rule's burdens, Compl. ¶¶ 28, 39–41—until August 2018, even the first step in Plaintiff's causal chain has yet to occur. 81 Fed. Reg. at 29,010–12.[6] The notion that each step will occur precisely as Plaintiff predicts is speculation in the purest sense.

Regardless, Plaintiff fails to demonstrate how any increased state Medicaid spending—if it ever comes to pass—would harm him *personally*. *See Bond*, 564 U.S. at 225; *Ass'n of Am. Physicians & Surgeons*, 768 F.3d at 642 (no standing where plaintiffs "invoke[d] a long and contestable chain of causation" and "d[id] not complain about anything done to them personally"). Plaintiff's status as a state taxpayer is plainly insufficient. *See* Compl. ¶ 32 (alleging "costs to taxpayers"). As the Supreme Court has squarely held, "state taxpayers have no standing under Article III to challenge state tax or spending decisions simply by virtue of their status as taxpayers." *DaimlerChrysler*, 547 U.S. at 346.

Plaintiff's status as a member of the West Virginia Legislature does not alter this result. *See* Compl. ¶ 9. For example, in *Raines v. Byrd*, 521 U.S. 811 (1997), the Supreme Court held that six members of Congress lacked standing to assert that the Line Item Veto Act unconstitutionally expanded the President's power. The Court explained that because the six plaintiffs did not represent a sufficient number of legislators to enact or defeat specific legislation, they could not allege that the statute nullified their votes or would do so in the future.

[6] As explained in the preamble to the final rule, the "FDA does not intend to initiate enforcement action for failure to have premarket authorization during the respective compliance periods. The compliance period for submission" of premarket tobacco applications ("PMTAs") is "24 months from the effective date of this final rule"—i.e., August 8, 2018.

Id. at 824. Instead, "the institutional injury they allege[d was] wholly abstract and widely dispersed" among the entirety of Congress. *Id.* at 829.

So too here. Plaintiff alleges that the FDA "usurped the power of the State of West Virginia to shift residents from more dangerous tobacco products to the healthier alternatives of vape and e-liquid products." Compl. ¶ 61. But as a single legislator, Plaintiff could not implement legislation designed to effect such a shift regardless of the deeming rule. Similarly, Plaintiff's allegation that the FDA is "effectively forcing the State of West Virginia to expend state tax dollars through Medicaid to pay the healthcare costs associated with [the] use of tobacco" does not affect Plaintiff specifically. *Id.* ¶ 33. A single member of the state legislature could not control the state's Medicaid expenditures. Rather, Plaintiff impermissibly attempts to assert "an institutional injury," despite lacking the authority to represent the state legislature as an institution. *Ariz. State Legislature v. Ariz. Indep. Redistricting Comm'n*, 135 S. Ct. 2652, 2664 (2015). Any injury brought about by the deeming rule "scarcely zeroe[s] in on any individual member" of the legislature, and thus Plaintiff cannot "tenably claim a personal stake in the suit." *Id.*

Indeed, it is doubtful that the entirety of the state legislature, or even the state itself, would have standing to bring the commandeering claim that Plaintiff asserts. Just as the deeming rule does not regulate Plaintiff himself, "the challenged regulations neither require nor forbid any action on the part of [the state]," making standing "substantially more difficult to establish." *Ass'n of Private Sector Colleges & Univs. v. Duncan*, 681 F.3d 427, 457–58 (D.C. Cir. 2012). Moreover, "Supreme Court anti-commandeering cases . . . also implicitly recognize that no true 'commandeering' injury-in-fact exists absent compulsion or coercion by the federal government." *West Virginia v. U.S. Dep't of Health and Human Servs.*, 145 F. Supp. 3d 94, 107

(D.D.C. 2015). Because West Virginia is not the "object" of the FDA's rule here, *Lujan*, 504 U.S. at 562, it is difficult to see how the rule itself could be viewed as compelling or coercing the state to take any action whatsoever.[7] The Court could not so conclude without accepting many of the same inferences that make Plaintiff's claims untenable, and once again any such injury would be far too speculative to provide the basis for standing.

Thus, Plaintiff's status as a taxpayer or state legislator gives him no greater standing to challenge the deeming rule. Whether for lack of a cognizable injury or for lack of causation, Plaintiff lacks standing, and the Court lacks jurisdiction.

II. PLAINTIFF'S CHALLENGE TO THE DEEMING RULE IS UNRIPE

There is yet another, independent reason to dismiss this case: For many of the same reasons that Plaintiff lacks standing, his challenge to the deeming rule is also unripe. "The ripeness doctrine is drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction." *Nat'l Park Hospitality Ass'n v. Dep't of the Interior*, 538 U.S. 803, 808 (2003) (quotation omitted). It "prevent[s] the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements." *Id.* The ripeness inquiry "evaluate[s] both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967). Here, Plaintiff satisfies neither prong of the inquiry, because the deeming rule does not operate on him in the first place, and his alleged injuries depend on "contingent future

[7] Indeed, "Medicaid is a voluntary program in which states are free to choose whether to participate. If [West Virginia] chose not to participate, there would be no federal regulation requiring the state to provide medical services" to tobacco users. *Padavan v. United States*, 82 F.3d 23, 28 (2d Cir. 1996) (citations omitted). Thus, the deeming rule itself "does not require the state to do anything that the state itself has not required, authorized, or provided by its own legislative command." *Freilich v. Upper Chesapeake Health, Inc.*, 313 F.3d 205, 214 (4th Cir. 2002).

events that may not occur as anticipated, or indeed may not occur at all." *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 580–81 (1985).

A "regulation is not ordinarily considered the type of agency action 'ripe' for judicial review under the [APA] until the scope of the controversy has been reduced to more manageable proportions, and its factual components fleshed out, by some concrete action applying the regulation to the claimant's situation in a fashion that harms or threatens to harm him." *Nat'l Park Hospitality*, 538 U.S. at 807; *see also Renne v. Geary*, 501 U.S. 312, 321–22 (1991) (challenge unripe where courts "possess no factual record of an actual or imminent application of [the provision] sufficient to present the . . . issues in 'clean-cut and concrete form'"). Here, not only does the deeming rule not regulate Plaintiff, but he makes no attempt to identify any particular e-cigarette or e-liquid product that it does regulate; instead, he simply urges the Court to weigh in on the FDA's statutory authority to regulate *all* e-cigarettes and e-liquids, regardless of any differences among those products. *See* Compl. ¶ 4 (describing differences among "vaping" systems and e-liquids). The Court should decline this invitation to "declar[e] the meaning of the law in a vacuum." *Ehrenfeld v. Mahfouz*, 489 F.3d 542, 546 (2d Cir. 2007). Indeed, even in suits brought by *manufacturers*, courts have dismissed such claims as unripe in the absence of a concrete enforcement action. *See, e.g., BBK Tobacco & Foods, LLP v. FDA*, 672 F. Supp. 2d 969, 976–77 (D. Ariz. 2009) (rejecting as unripe plaintiff's claim that flavored rolling papers could not be considered "component parts" of a cigarette, because "the FDA has not taken any specific action with respect to [plaintiff] or any of its products").

In any event, Plaintiff's alleged injury is too "dependent on future uncertainties" to be considered ripe. *Doe v. Va. Dep't of State Police*, 713 F.3d 745, 758 (4th Cir. 2013). As the Fourth Circuit has explained, "[w]here an injury is contingent upon a decision to be made by a

third party that has not yet acted, it is not ripe as the subject of decision in a federal court." *Id*. Here, Plaintiff's theory of harm depends almost entirely on hypothetical third-party decisions that have not yet been made: e-cigarette manufacturers' decisions to take products off the market, e-cigarette manufacturers' decisions to raise prices, e-cigarette users' decisions to resume smoking conventional cigarettes, the state of West Virginia's taxation decisions, and so on. Plaintiff cannot predict the outcomes of these decisions with any certainty, least of all years before they will be made.

Thus, even if the Court were to find that Plaintiff had standing, it should dismiss his challenge to the deeming rule as unripe.

CONCLUSION

For the foregoing reasons, this case should be dismissed in its entirety for lack of jurisdiction.

Dated: October 28, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 28, 2016, I filed the foregoing document with the Clerk of Court via the CM/ECF system, which will send notification of such filing to the following CM/ECF participants:

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